IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ROCHE PALO ALTO LLC, GILEAD PALO ALTO, INC. and GILEAD SCIENCES, INC., Plaintiffs, v. LUPIN PHARMACEUTICALS, INC. and LUPIN LTD., Defendants.	Civ. A. No. 2:10-03561 (EJS) (SCM) *DOCUMENT FILED ELECTRONICALLY*

LUPIN'S RESPONSIVE CLAIM CONSTRUCTION SUBMISSION REGARDING CONSTRUCTION OF PLASMA LEVEL CLAIM TERMS

Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Geri L. Albin (gla@saiber.com)
SAIBER LLC
One Gateway Center, 10th Floor
Newark, New Jersey 07102
(973) 622-3333
(973) 622-3349

William A. Rakoczy
(wrakoczy@rmmslegal.com)
Paul J. Molino (paul@rmmslegal.com)
Deanne M. Mazzochi
(dmazzochi@rmmslegal.com)
Thomas R. Burns (tburns@rmmslegal.com)
Jeffrey A. Marx (jmarx@rmmslegal.com)
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60654
(312) 222-6301

Attorneys for Defendants
Lupin Pharmaceuticals, Inc. and Lupin Ltd.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Statutes

I. Introduction.

Plaintiffs Roche Palo Alto LLC, Gilead Palo Alto, Inc. and Gilead Sciences, Inc. (collectively "Plaintiffs") acknowledge the claim language they seek to construe involves blood plasma ***levels***. (ECF No. 359, Pls.' Br. at 1-2 (hereafter "Pl. Br.")). Plaintiffs wrongly imply that any Asserted Patent specification "defines the plasma levels as means" based on a description of "Plasma ranolazine ***concentration***" taken from a group of 5-10 humans as a mean value. (*Id.* at 1). Plaintiffs' approach requires this Court to (1) strike "plasma level"; (2) add "plasma ranolazine concentration"; then (3) import specification descriptions of "plasma ranolazine concentration." Since the Federal Circuit prohibits this Court from performing steps (1) and (2), *see, e.g.*, *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("courts may not redraft claims"); *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995) (same), the necessary preconditions to apply step (3)'s descriptions never arise. Even if they had, Plaintiffs still have not justified their mean-versus-individual approach in the context of the Asserted Patents, particularly where both parties' experts agree the claim language "***a*** human," "***a*** human patient" or "***the*** human patient" refers to an individual patient. (Trial Tr. vol. 4, 84:13-22, 88:9-89:5 (Zusman); Trial Tr. vol. 3, 44:21-45:19 (Weiner)). Lupin's, not Plaintiffs', construction should be adopted.

II. PK parameters are not presumptively reported as mean values.

Plaintiffs argue that pharmacokinetic ("PK") parameters are "typically assessed" as means, but their citations do not support that premise. Dr. Weiner acknowledged that when PK parameters are ***summarized***, they are reported with mean values; likewise, when values for a group of patients are summarized, average values are reported. (Pl. Br. at 2). But the claims do not purport to summarize treating groups of patients; as Defendants' prior brief explained, the method treats individual patients. (ECF No. 360, Def. Br. at 1 (hereafter "Def. Br."); Trial Tr. vol. 3, 190:6-192:8 (Mayersohn)). Dr. Weiner admitted patients are not treated as groups. (Trial

Tr. vol. 3, 44:21-45:19 (Weiner)). Dr. Weiner's testimony also belies the premise that the person of ordinary skill presumptively views PK parameters as describing a mean of a group of patients versus individuals; he admitted, for example, that from the Lupin proposed labeling, he could not tell whether a PK parameter was intended to refer to individual or mean patient results.[1] Thus, Plaintiffs have not established a "common convention" to support the notion that any reference to a PK parameter is presumptively a "mean" value.

III. The specification does not equate the claimed plasma *levels* to a mean *concentration*.

Plaintiffs insist the specification both defines and stresses the importance of mean values. (Pl. Br. at 3). But Plaintiffs continue to cite text describing the non-claim language of ranolazine ***concentrations***, not ranolazine plasma levels. Likewise, the Examples Plaintiffs reference, as Defendants' opening brief explained, reference ranolazine *concentrations*, not ranolazine plasma levels, and accompany that description with repeated statements they are mean values as well—language missing from the claims. (Pl. Br. at 3; Def. Br. at 3 n.1).

Plaintiffs also complain that having to focus on individual patient values would render the patent examples a nullity. (Pl. Br. at 3). First, ***none*** of the patent Examples testing the SR formulation involved actual patients; thus, individuals in those trials never would have infringed whether the claims are construed individually or as means. (Trial Tr. vol. 7, 118:15-24 (Chaitman); Trial Tr. vol. 8, 250:14-21 (Wolff); *see also, e.g.*, DTX12A). Second, Dr. Weiner opined that several individuals who took the SR formulation D in the MARISA clinical trials fell within the scope of the claims. (Trial Tr. vol. 3, 23:9-24:6, 59:5-61:7 (Weiner)). Thus, there is

[1] (Trial Tr. vol. 3, 34:2-13 (Weiner) ("not sure" whether a confidence interval range was correct, and agreeing it must refer to individual patients because it looks too wide to be a confidence interval based on a mean); *see also id.* at 35:11-25 (Weiner) ("Q. [B]ecause those numbers, 400 to 6100, don't explicitly say mean or individual, you are not sure how to interpret them? A. Well, that plus the fact as I said, they are not symmetric about the 2600 as well. So I don't know how to interpret that.")). Nor should there be any serious dispute that before patient values can be summarized, they must be individually collected. (Trial Tr. vol. 3, 12:11-22 (Weiner)).

no presumptive exclusion of an alleged embodiment of the invention from the claims under Defendants' construction. Third, if Plaintiffs wanted claims to cover every single patient taking ranolazine SR, they, not Lupin, had the obligation to draft claims wide enough to cover all patients; it is not this Court's role to save Plaintiffs from poor claim drafting choices. *Chef Am.*, 358 F.3d at 1374-75; *see also Mars, Inc. v. Coin Acceptors, Inc.*, 478 F. Supp. 2d 689, 715-16 (D.N.J. 2007) (Lifland, J.) (adopting one construction over another because the rejected construction "would have the result of effectively excising [] words from the claims."). Fourth, the 550-7500 ng/mL plasma level range is *exactly* the one the specification assigns to a patient, in text separate and apart from the "plasma ranolazine concentration" description. (Def. Br. at 2-3).

Plaintiffs also mischaracterize Lupin's plasma-related defense. (Pl. Br. at 3). Plasma levels arise in the context of methods of using doses in the '057, '328 and '258 patents. When the "product has substantial noninfringing uses, intent to induce infringement cannot be inferred even when the defendant has actual knowledge that some users of its product may be infringing the patent." *Warner–Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003).

As for the meaning of "a" patient, the claims here are distinguishable from claimed objects where "a" would not be expected refer to a single item. *See, e.g.*, *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000) ("a" chamber in a mattress was not presumed singular); *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1343 (Fed. Cir. 2008) ("a pre-soaked fabric roll" was not limited to a single roll). In this art, "a" patient or human is singular; doctors unquestionably treat patients as individuals, not as interchangeable groups or commodities. (Trial Tr. vol. 4, 84:13-85:9, 88:18-89:5 (Zusman); Trial Tr. vol. 3, 44:23-45:17 (Weiner)); *cf. Instituform Techs., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1105 (Fed. Cir. 1996) ("nothing in the text of claim 1 suggests the use of more than one cup…, claim 1 refers to 'a cup' and 'the cup' repeatedly, suggesting that only one cup is involved")). But even

if Plaintiffs could import one part of the plasma concentration description, it should import all of it—doing so means its claims are limited to only instances where a group of 5-10 people participate in a clinical trial with mean plasma concentrations presented and summarized.

IV. Plaintiffs' other cases also do not suggest plasma levels should be treated as means.

Wyeth v. Lupin Ltd., 579 F. Supp. 2d 711 (D. Md. 2008) is distinguishable as Defendants already explained. (Def. Br. at 4-5). If Plaintiffs adhere to their theory that "[t]he specification presents ***no*** individual values" at all (Pl. Br. at 3), then the claims should be held invalid under 35 U.S.C. § 112 for lack of written description support. (Def. Br. at 4-5). *Wyeth v. Sandoz, Inc.*, 703 F. Supp. 2d 508 (E.D.N.C. 2010) notes other district courts construed blood plasma concentrations to "refer to individual patients rather than an average taken from multiple individuals because of the 'plain reading' of the 'in a patient'" claim language. *Id.* at 528-29 (citing *Wyeth v. Apotex Inc.,* No. 08–22308, 2009 WL 8759472 *11 (S.D. Fla. Aug. 13, 2009) ("*in a patient's* blood plasma" text "clearly supports" that "in a patient" refers to individual patients)). Plaintiffs did not discuss, *e.g.,* Chief Judge Brown's holding in *Acordia Therapeutics Inc. v. Apotex Inc*., No. 07-4937 (GEB-MCA), 2011 WL 4074116, at *4 (D.N.J. Sept. 6, 2011).[2]

Plaintiffs wrongly suggest Lupin lacks noninfringement defenses (save Dr. Weiner's lack of credibility) if this Court imports plasma concentration descriptions into the Asserted Claims. (Pl. Br. at 5). The text Plaintiffs point to in the specification describes groups of 5-10 patients to be aggregated as mean values in the context of small clinical trials. Plaintiffs put forth no evidence that Lupin will be encouraging the use of its products this way. Dr. Zusman testified

[2] The decisions in *Wyeth v. Lupin* and *Wyeth v. Sandoz* were district court decisions that did not reach the Federal Circuit. (*See Wyeth v. Lupin*, No. 07-632-WDQ, Consent Judgment (D. Md. April 23, 2009); *Wyeth v. Sandoz*, No. 07-234-D, Consent Order (E.D.N.C. Aug. 9, 2011)). By contrast, the Federal Circuit summarily affirmed *Acordia Therapeutics Inc. v. Apotex Inc*., No. 07-4937 (GEB-MCA), 2011 WL 4074116 (D.N.J. Sept. 6, 2011). *See Acordia Therapeutics Inc. v. Apotex Inc.*, 476 F. App'x 746 (Fed. Cir. 2012).

that doctors will not group or otherwise try to treat groups of patients; his testimony is unrebutted. (Trial Tr. vol. 4, 81:1-82:8, 84:13-85:9, 88:18-89:5 91:9-92:5 (Zusman)). Plaintiffs' expert Dr. Chaitman conceded that doctors will not try to target or measure patient plasma concentrations. (Trial Tr. vol. 7, 166:6-19 (Chaitman)). Likewise, Dr. Weiner conceded that there are ***no instructions in the Lupin labeling encouraging achieving plasma levels of any kind***. (Trial Tr. vol. 3, 25:11-28:20 (Weiner); Trial Tr. vol. 4, 90:25-91:8 (Zusman)). Dr. Weiner admitted that he had not calculated the number of patients (whether as averages or individuals) in the current patient population who would meet the claim requirements. (Trial Tr. vol. 3, 21:12-19, 67:8-17 (Weiner)). Thus, even if this Court considers whether in the future there is a "group" of 5-10 infringing patients, Plaintiffs failed to show the Lupin labeling encourages such infringement. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) (the "pertinent question" in ANDA cases with respect to induced infringement is "whether the proposed label instructs users to perform the patented method" and "promote[s]" or "encourage[s]" others to practice that method.) (citing *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 n.2 (Fed. Cir. 2009)).

As for claim 31, the inconsistency in Plaintiffs' story is self-evident. Dr. Weiner opined one should import the 550 ng threshold into claim 31. (Tr. Trans. vol. 7, 64:14-65:1 (Weiner)). Dr. Wolff testified the lower range extended down to zero. (Tr. Trans. vol. 8, 118:4-23 (Wolff)). Either way, the claim is either not infringed or invalid (for covering every prior art formulation, including the IR products). (*See id.*; DTX30-0002-03; DTX616-0007).

V. Conclusion.

Lupin thus respectfully requests that the Court construe the claims' plasma level-related claim language as requiring achieving the claimed plasma levels in individual patients.

Respectfully submitted,

Dated: June 14, 2013

SAIBER LLC

Attorneys for Defendants Lupin Pharmaceuticals, Inc. and Lupin Ltd.

By: s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Geri L. Albin (galbin@saiber.com)
SAIBER LLC
One Gateway Center, 10th Floor
Newark, New Jersey 07102-5311
(973) 622-3333

William A. Rakoczy (wrakoczy@rmmslegal.com)
Paul J. Molino (paul@rmmslegal.com)
Deanne Mazzochi (dmazzochi@rmmslegal.com)
Thomas R. Burns (tburns@rmmslegal.com)
Jeffrey A. Marx (jmarx@rmmslegal.com)
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60654
(312) 222-6301